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EXAMINER	
YANG, NELSON C	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,931	FOLLONIER ET AL.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-59* is/are pending in the application.

4a) Of the above claim(s) *36-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/21/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group I, claims 1-35 in the reply filed on May 5, 2009 is acknowledged.

Claims 36-59 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 5, 2009.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 5, 9, 10, 27, 30, 31, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 5, 27, recite the limitation "the material" in the steps b) of the claim. There is insufficient antecedent basis for this limitation in the claim.

5. Claims 10, 11, 32, 33, recite the limitation "the at least one capture agent" in the claim. There is insufficient antecedent basis for this limitation in the claim. It is currently interpreted that "the at least one capture agent" refers to the at least one binding agent recited in claim 1.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 2, 5-11, 13-16, 19-23, 25, 28-33, 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Lockhart [US 6,974,673].

With respect to claim 1, Lockhart teaches a hollow optical waveguide with a light-input end and a light-output end, and a first biomolecular constituent attached to the inner wall of the hollow optical waveguide (column 2, lines 31-42). A fluid containing a target substance enters the cavity of the waveguide through a port and exits through another port (column 4, lines 20-25, fig. 1). Lockhart further teaches light from a source such as a laser is introduced into the light-input ends (light connecting element) of the waveguide

8. With respect to claim 2, a sample comprising a liquid containing a target substance enters the cavity of the waveguide through a port and exits through another port (column 4, lines 20-25, fig. 1).

9. With respect to claim 5, Lockhart further teaches light from a source such as a laser is introduced into the light-input ends (primary light connecting element) of the waveguide (column 4, lines 25-30), and light emanating from the light-output end (secondary light connecting element) is received by opto-electric detectors (column 4, lines 25-45), such that if biomolecular constituents in fluid delivered to the waveguide (fluid dispensing element) (column

4, lines 20-25) bind to the constituents on the surface of the waveguide, a change occurs in the light propagating through the waveguide (column 4, lines 40-56). Lockhart further teaches a hollow fiber surrounded by cladding (column 5, lines 6-25).

10. With respect to claim 6, Lockhart et al each that the first biomolecular constituent can be directly attached to the waveguide (column 9, lines 20-27), which would be an organic coating.

11. With respect to claims 7, 8, Lockhart teaches a hollow optical waveguide comprising a fiber surrounded by cladding (column 2, lines 31-42, column 5, lines 6-25).

12. With respect to claim 9, Lockhart et al. teach a fluid within the cavity of a hollow optical waveguide, wherein light is capable of traveling through the capillary and optical fiber (column 2, lines 30-43).

13. With respect to claim 10, Lockhart et al each that the first biomolecular constituent can be directly attached to the waveguide (column 9, lines 20-27).

14. With respect to claim 11, Lockhart teaches that the first biomolecular constituent can be indirectly attached to the waveguide via a linker (interstitial layer) (column 9, lines 27-55).

15. With respect to claim 13, Lockhart teaches that if biomolecular constituents in fluid delivered to the waveguide (fluid dispensing element) (column 4, lines 20-25) bind to the constituents on the surface of the waveguide, a change occurs in the light propagating through the waveguide (column 4, lines 40-56).

16. With respect to claim 14, Lockhart teaches a hollow optical waveguide with a light-input end and a light-output end, and a first biomolecular constituent attached to the inner wall of the hollow optical waveguide (column 2, lines 31-42). A fluid containing a target substance enters the cavity of the waveguide through a port and exits through another port (column 4, lines 20-25,

fig. 1). Lockhart further teaches light from a source such as a laser is introduced into the light-input ends (primary light connecting element) of the waveguide (column 4, lines 25-30), and light emanating from the light-output end (secondary light connecting element) is received by opto-electric detectors (column 4, lines 25-45), such that if biomolecular constituents in fluid delivered to the waveguide (fluid dispensing element) (column 4, lines 20-25) bind to the constituents on the surface of the waveguide, a change occurs in the light propagating through the waveguide (column 4, lines 40-56).

17. With respect to claims 15-16, Lockhart teaches light from a source such as a laser (column 4, lines 25-30), which could be considered an array of a single laser.

18. With respect to claim 19, Lockhart further teaches light-input ends (primary light connecting element) (column 4, lines 25-30), and light-output ends (secondary light connecting element) (column 4, lines 25-45). The light-input end and the light-output end could therefore be considered to be optical windows.

19. With respect to claim 20, the ports through which fluid enters are located along the same fiber as the light-input ends and light output ends (fig. 1), which would be considered liquid dispensing elements.

20. With respect to claim 21, Lockhart further teaches light from a source such as a laser is introduced into the light-input ends (primary light connecting element) of the waveguide (column 4, lines 25-30), and light emanating from the light-output end (secondary light connecting element) is received by opto-electric detectors (column 4, lines 25-45).

21. With respect to claim 22, fluid containing a target substance enters the cavity of the waveguide through a port and exits through another port (fluid dispensing element) (column 4, lines 20-25, fig. 1).

22. With respect to claim 23, Lockhart further teaches a sample container (column 7, lines 55-58).

23. With respect to claim 25, a sample comprising a liquid containing a target substance enters the cavity of the waveguide through a port and exits through another port (column 4, lines 20-25, fig. 1).

24. With respect to claim 28, Lockhart further teaches light from a source such as a laser is introduced into the light-input ends (primary light connecting element) of the waveguide (column 4, lines 25-30), and light emanating from the light-output end (secondary light connecting element) is received by opto-electric detectors (column 4, lines 25-45), such that if biomolecular constituents in fluid delivered to the waveguide (fluid dispensing element) (column 4, lines 20-25) bind to the constituents on the surface of the waveguide, a change occurs in the light propagating through the waveguide (column 4, lines 40-56). Lockhart further teaches a hollow fiber surrounded by cladding (column 5, lines 6-25).

25. With respect to claim 29, Lockhart et al each that the first biomolecular constituent can be directly attached to the waveguide (column 9, lines 20-27), which would be an organic coating.

26. With respect to claim 30, Lockhart teaches a hollow optical waveguide comprising a fiber surrounded by cladding (column 2, lines 31-42, column 5, lines 6-25).

27. With respect to claim 31, Lockhart et al. teach a fluid within the cavity of a hollow optical waveguide, wherein light is capable of traveling through the capillary and optical fiber (column 2, lines 30-43).

28. With respect to claim 32, Lockhart et al each that the first biomolecular constituent can be directly attached to the waveguide (column 9, lines 20-27).

29. With respect to claim 33, Lockhart teaches that the first biomolecular constituent can be indirectly attached to the waveguide via a linker (interstitial layer) (column 9, lines 27-55).

30. With respect to claim 35, Lockhart teaches that if biomolecular constituents in fluid delivered to the waveguide (fluid dispensing element) (column 4, lines 20-25) bind to the constituents on the surface of the waveguide, a change occurs in the light propagating through the waveguide (column 4, lines 40-56).

31. Claims 3, 4, 26, 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Lockhart [US 6,974,673] in light of Kumar et al [US 5,624,850].

With respect to claims 3, 4, 26, 27, Lockhart teaches a hollow waveguide that is a glass capillary. Although Lockhart does not teach that the capillary is capable of capillary action, one of ordinary skill would know that capillary fibers are capable of capillary action, as evidenced by Kumar et al, who teach that the samples may be taken up in a capillary via capillary force (column 8, lines 45-56). It should also be noted that claims 3-4, 25, 26, refer to an intended use of the capillary. Since the capillary of Lockhart is capable of capillary action, it meets the claim.

Claim Rejections - 35 USC § 103

32. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

33. Claims 12, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lockhart [US 6,974,673] in view of Kumar et al [US 5,624,850].

With respect to claims, 12, 34, Lockhart teaches a hollow optical waveguide with a light-input end and a light-output end, and a first biomolecular constituent attached to the inner wall of the hollow optical waveguide (column 2, lines 31-42). A fluid containing a target substance enters the cavity of the waveguide through a port and exits through another port (column 4, lines 20-25, fig. 1). Lockhart further teaches light from a source such as a laser is introduced into the light-input ends (primary light connecting element) of the waveguide (column 4, lines 25-30), and light emanating from the light-output end (secondary light connecting element) is received by opto-electric detectors (column 4, lines 25-45), such that if biomolecular constituents in fluid delivered to the waveguide (fluid dispensing element) (column 4, lines 20-25) bind to the constituents on the surface of the waveguide, a change occurs in the light propagating through the waveguide (column 4, lines 40-56). Lockhart does not teach coating the waveguide with an additional layer that prevents or retards non-specific adsorption or binding of the target and/or other components of the sample.

Kumar et al, however, do teach coating the capillary surface with a blocking solution to prevent non-specific adsorption (column 5, lines 24-40). Kumar et al further teach that non-

specific adsorption as it may result in nonspecific binding of the label to the surface (column 5, lines 24-35), which would increase background noise.

Therefore, it would have been obvious to one of ordinary skill in the art to coat the capillary surface of Lockhart with a blocking solution to prevent non-specific adsorption, as suggested by Kumar et al, in order to prevent nonspecific binding of the label to the surface, which would increase background noise, so that a more accurate signal could be obtained.

34. Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lockhart [US 6,974,673] in view of Aker et al [US 6,558,626].

With respect to claims 17-18, Lockhart teaches that light emanating from the light-output end (secondary light connecting element) is received by an array of opto-electric detectors (column 4, lines 25-45), such that if biomolecular constituents in fluid delivered to the waveguide (fluid dispensing element) (column 4, lines 20-25) bind to the constituents on the surface of the waveguide, a change occurs in the light propagating through the waveguide (column 4, lines 40-56). Lockhart fails to teach that the opto-electric detectors can be photomultiplier tubes, cameras, or photodiodes.

Aker et al, however, do teach the use of detectors such as photomultiplier tubes (column 17, lines 16-23), and further teach that detectors such as photomultiplier tubes are sensitive and have a wide dynamic range (column 17, lines 23-31).

Therefore, it would have been obvious to one of ordinary skill in the art for the opto-electric detectors of Lockhart to be photomultiplier tubes, as suggested by Aker et al, in order to have detectors that are sensitive and that have a wide dynamic range.

35. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lockhart [US 6,974,673] in view of Saaski et al [US 6,484,594].

With respect to claim 24, Lockhart teaches a hollow optical waveguide with a light-input end and a light-output end, and a first biomolecular constituent attached to the inner wall of the hollow optical waveguide (column 2, lines 31-42). A fluid containing a target substance enters the cavity of the waveguide through a port and exits through another port (column 4, lines 20-25, fig. 1). Lockhart further teaches light from a source such as a laser is introduced into the light-input ends (primary light connecting element) of the waveguide (column 4, lines 25-30), and light emanating from the light-output end (secondary light connecting element) is received by opto-electric detectors (column 4, lines 25-45), such that if biomolecular constituents in fluid delivered to the waveguide (fluid dispensing element) (column 4, lines 20-25) bind to the constituents on the surface of the waveguide, a change occurs in the light propagating through the waveguide (column 4, lines 40-56). Lockhart fails to teach a disposal reservoir.

Saaski et al, however, do teach the use of a waste container (column 30, lines 40-45). Saaski et al further teach that clearing of any old, historical target material is important in any situation where it is desired that the detection apparatus detect target material that is currently entering the invention, rather than target material that has entered it in the past (column 30, lines 43-65).

Therefore, it would have been obvious to one of ordinary skill in the art to have a waste container (disposal reservoir) in the invention of Lockhart and that the fluid exiting the waveguide of Lockhart go to a waste container rather than be recirculated, as suggested by Saaski et al, in order to clear the waveguide of old, historical target material, such that the

detection apparatus detects target material currently entering the waveguide rather than target material that has entered it in the past.

Double Patenting

36. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

37. Claims 1-6, 8-33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13, 16-33, 59, 60, 62 of copending Application No. 10/670,912. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application recites a system comprising a light emitting element, a measuring cell comprising a tube with a first and second opening and an inner surface coated with at least one binding agent (claim 13). The conflicting claims further recite a light detecting element selected from a photomultiplier tube, a camera, and a photodiode, and primary and secondary light connecting elements selected from an optical

window, a lenslet array, a spectral filter, a partially reflecting mirror, an intensity filter, and a grating coupler (claim 16-18). The conflicting claims further recite a sample and disposal reservoir, along with a liquid or gaseous sample (claims 23-24), wherein the flow of the fluid may be regulated by pressure gravity capillary forces (claims 25-26), and wherein the inner surface of the at least one tube comprises one or more organic or inorganic layers (claim 28) wherein the binding agent may be directly bound to the inner surface or indirectly bound by interstitial layers (claim 30-31), and wherein the tube may comprise a fluid core waveguide or a photonic bandgap crystal (claim 29).

Therefore, the conflicting claims recite a narrower embodiment that would render the broader scope encompassed by the claims of the instant invention obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

38. No claims are allowed.

39. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571)272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571)272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

40. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nelson Yang/
Primary Examiner, Art Unit 1641